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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No. 01-034)

PATENT

In Re Application of: Bacus, S. )  
Serial No. 09/760,119 )  
Filed: January 12, 2001 )  
For: METHOD FOR DETERMING THE )  
RESPONSE TO CANCER THERAPY )

Examiner: Canella, K.A.  
Art Unit: 1642  
Confirmation number: 1978

TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

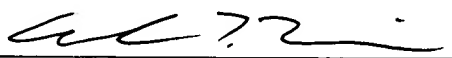
Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:  
☒ Supplemental Information Disclosure Statement;  
☒ Form PTO-1449 including (7 cited references); and  
☒ Return Postcard
2. No fees are due at this time.
3. **GENERAL AUTHORIZATION TO CHARGE OR CREDIT FEES:** Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.
4. **CERTIFICATE OF MAILING UNDER 37 CFR § 1.8:** I hereby certify that I directed that this Transmittal Letter and the correspondence identified above be deposited with the United States Postal Service as "First Class Mail," addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Respectfully submitted,

Date: February 13, 2004

  
Andrew W. Williams  
Registration No. 48,644

## PATENT

**In Re Application of:**

**Bacus, S.**

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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C. F.R. §§ 1.97-98, the applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. § 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

It is requested that each document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully

complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Portions of the references may be material to the examination of the pending claims, however no such admission is intended. 37 C.F.R. 1.97 (h). The references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative importance of any portion of the references. This Statement is not a representation that the cited references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. sections 102 or 103.

Applicants do not believe any fee is due with this submission. If this belief is in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. § 1.97 is applicable, the undersigned representative by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

### **Other Documents**

Bacus et al., "Neu differentiation factor (Heregulin) activates a p53-dependent pathway in cancer cells," *Oncogene* 12(12):2535-47, 1996.

- Cited by the Canadian Intellectual Property Office as not complying with Paragraph 28.2(1)(b) of the Canadian Patent Act for allegedly disclosing the claimed subject matter before the claim date.

Chang et al., "p21Waf1/Cip1/Sdi1-induced growth arrest is associated with depletion of mitosis-control proteins and leads to abnormal mitosis and endoreduplication in recovering cells," *Oncogene* 19:2165-2170, 2000.

- Cited by the Canadian Intellectual Property Office as not complying with Section 28.3 of the Canadian Patent Act for allegedly rendering the subject matter of the claims obvious on the claim date to a person skilled in the art or science to which they pertain in view of additional cited art and common general knowledge.

Kopp et al., "Transforming Growth Factor  $\beta$ 2 (TGF- $\beta$ 2) Levels in Plasma of Patients with Metastatic Breast Cancer Treated with Tamoxifen," Cancer Research 55(20):4512-4515, 1995.

- Cited by the Canadian Intellectual Property Office as not complying with Section 28.3 of the Canadian Patent Act for allegedly rendering the subject matter of the claims obvious on the claim date to a person skilled in the art or science to which they pertain in view of additional cited art and common general knowledge.

Lei et al., "The expression of suppressor gene p16, p21 and p53 in nasopharyngeal carcinoma," Lin Chuang Er Bi Yan Hou Ke Za Zhi 13(9):406-8, 1999.

- Cited by the Canadian Intellectual Property Office as not complying with Section 28.3 of the Canadian Patent Act for allegedly rendering the subject matter of the claims obvious on the claim date to a person skilled in the art or science to which they pertain in view of additional cited art and common general knowledge. An English-language abstract is included with this non-English language reference.

Meyn et al., "Apoptosis in murine tumors treated with chemotherapy agents," Anti-Cancer Drugs 6:443-450, 1995.

- Cited by the Canadian Intellectual Property Office as not complying with Section 28.3 of the Canadian Patent Act for allegedly rendering the subject matter of the claims obvious on the claim date to a person skilled in the art or science to which they pertain in view of additional cited art and common general knowledge.

Shibata et al., "Suppression of mammary carcinoma growth in vitro and in vivo by inducible expression of the Cdk inhibitor p21," Cancer Gene Therapy 8:23-35, 2001.

- Cited by the Canadian Intellectual Property Office as not complying with Paragraph 28.2(1)(b) of the Canadian Patent Act for allegedly disclosing the claimed subject matter before the claim date.

Timmermann et al., "Re-expression of endogenous p16ink4a in oral squamous cell carcinoma lines by 5-aza-2'-deoxycytidine treatment induces a senescence-like state," Oncogene 17(26):3445-53, 1998.

- Cited by the Canadian Intellectual Property Office as not complying with Section 28.3 of the Canadian Patent Act for allegedly rendering the subject matter of the claims obvious on the claim date to a person skilled in the art or science to which they pertain in view of additional cited art and common general knowledge.

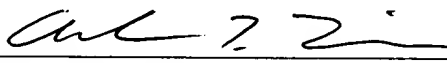
Certificate Pursuant to 37 C.F.R. §1.97(e)(1)


The undersigned hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

Respectfully submitted,

**McDonnell Boehnen Hulbert & Berghoff**

Date: February 13, 2004

By:   
Andrew W. Williams  
Registration No. 48,644

<b>FORM PTO-1449</b> (Rev. 2-32)	<b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>	<b>Atty. Docket No.</b> 01-034	<b>Serial No.</b> 09/760,119
 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use several sheets if necessary)		<b>Applicant:</b> Sarah S. Bacus <b>Filing Date:</b> 01/12/2001 <b>Group:</b> 1642	

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

1.	Bacus et al., "Neu differentiation factor (Heregulin) activates a p53-dependent pathway in cancer cells," Oncogene 12(12):2535-47, 1996.
2.	Chang et al., "p21 <sup>Waf1/Cip1/Sdi1</sup> -induced growth arrest is associated with depletion of mitosis-control proteins and leads to abnormal mitosis and endoreduplication in recovering cells," Oncogene 19:2165-2170, 2000.
3.	Kopp et al., "Transforming Growth Factor $\beta$ 2 (TGF- $\beta$ 2) Levels in Plasma of Patients with Metastatic Breast Cancer Treated with Tamoxifen," Cancer Research 55(20):4512-4515, 1995.
4.	Lei et al., "The expression of suppressor gene p16, p21 and p53 in nasopharyngeal carcinoma," Lin Chuang Er Bi Yan Hou Ke Za Zhi 13(9):406-8, 1999.
5.	Meyn et al., "Apoptosis in murine tumors treated with chemotherapy agents," Anti-Cancer Drugs 6:443-450, 1995.
6.	Shibata et al., "Suppression of mammary carcinoma growth in vitro and in vivo by inducible expression of the Cdk inhibitor p21," Cancer Gene Therapy 8:23-35, 2001.
7.	Timmermann et al., "Re-expression of endogenous p16 <sup>ink4a</sup> in oral squamous cell carcinoma lines by 5-aza-2'-deoxycytidine treatment induces a senescence-like state," Oncogene 17(26):3445-53, 1998.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.